

## Message Text

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PAGE 01 STATE 044833

46

ORIGIN HEW-06

INFO OCT-01 ARA-10 ISO-00 OES-05 /022 R

66614

DRAFTED BY: DHEW/FDA/JRWEINROTH MD

APPROVED BY: OES/SCI:BMP:MBEAUBIEN

DHEW/OIH/MACODDING

ARAA/NC:TWSONANDRES INFO

----- 087503

R 272207Z FEB 75

FM SECSTATE WASHDC

TO AMEMBASSY CARACAS

UNCLAS STATE 044833

E.O. 11652: NA

TAGS: OGEN, EIND, ETRD, TBIO, VE

SUBJ: FDA ADVISORY-IMPROPERLY DATED AND SEQUENCED ALLERGENIC  
EXTRACT DIAGNOSTIC KIT

1. FDA ADVISES THAT A PRODUCT ALLERGENIC EXTRACTS SCRATCH  
DIAGNOSTICS AND DIAGNOSTIC KITS, CAT NO 960100, MANUFACTURED  
BY DOME LABORATORIES, DIV OF MILES LABORATORIES, WEST HAVEN,  
CONN 06516 ARE BEING RECALLED TO THE USER LEVEL.
2. THE KITS CONSIST OF 44 VIALS OF VARIOUS ALLERGENIC EXTRACTS  
PLUS ONE CONTROL VIA SET UP ON A PRE-DETERMINED SERIES IN A  
WOODEN CARRYING CASE. THE KIT INCLUDES AN INSTRUCTION LEAFLET  
ENTITLED "INSTRUCTIONS FOR ALLERGENIC SCRATCH DIAGNOSTIC TESTS"  
DATED MAY 1972. A PLASTIC SKIN REACTION GUIDE RULER AND ALLERGY  
PRESCRIPTION FORMS ARE INCLUDED.
3. THE FOL LOT NUMBERS ARE INVOLVED. 905015, 903074, 904074,  
905074, 906074, 907074, 908074, 909074, 910074,  
AND 911074. LOT 905015 WAS DISTRIBUTED JAN AND FEB 1975; ALL  
OTHER LOTS WERE DISTRIBUTED JULY 1974.
4. THE REASON FOR THIS ADVISORY IS THAT ALL LOTS CONTAIN ONE VIAL  
OF RABBIT EPITHELIA EXTRACT WHICH BEARS AN EXPIRATION DATE OF 8/79

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PAGE 02 STATE 044833

WHICH IS IN EXCESS OF THAT PERMITTED BY THE BUREAU OF BIOLOGICS

REGULATIONS. SPECIFICALLY, WITH REGARD TO LOT 905015, THIS LOT IN ADDITION TO THE FOREGOING PROBLEM, CONTAINS, IN SOME KITS, A VIAL OF PENICILLIN NOTATUM EXTRACT WHICH BEARS AN EXPIRATION OF 9/74, WHICH, IF PROPERLY LABELED, COULD BEAR A DATE AS LATE AS 6/76. IN ADDITION, IN SOME OF THE KITS BEARING THIS LOT NUMBER, SOME VIALS ARE OUT OF THE NORMAL SEQUENCE AND SOME HAVE DUPLICATE VIALS. IN THE CASE WHERE THERE ARE DUPLICATIONS, A VIAL OF ANOTHER EXTRACT WOULD BE MISSING.

5. FOREIGN CONSIGNEE, AS FOLLOWS:

INDUSTRIAS MILES VENEZOLANA, C.A., APARTADO 80025, CARACAS, VENEZUELA.

6. POST IS REQUESTED TO DETERMINE IF FOREIGN CONSIGNEE HAS RECEIVED INFO RELATIVE TO THE PROBLEM WITH THE KITS AND INSTRUCTIONS AS TO NECESSARY ACTION WITH REGARD TO ULTIMATE USERS (PHYSICIANS). END KISSINGER

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## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 JAN 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** DRUGS, FOOD & DRUG REGULATIONS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 27 FEB 1975  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
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**Drafter:** DHEW/FDA/JRWEINROTH MD  
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**Executive Order:** N/A  
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**Film Number:** D750071-0227  
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**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** FDA ADVISORY-IMPROPERLY DATED AND SEQUENCED ALLERGENIC EXTRACT DIAGNOSTIC KIT  
**TAGS:** OGEN, EIND, ETRD, TBIO, VE, DOME LABORATORIES, INDUSTRIAS MILES VENEZOLANA C A  
**To:** CARACAS  
**Type:** TE  
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